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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,742	12/21/2000	Debra M. Eckert	0399.1192-008	8580

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EXAMINER	
CELSA, BENNETT M	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 09/24/2002 15

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.	Applicant(s)
09/746,742	Eckert et al.
Examiner	**Art Unit**
Bennett Celsa	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-97* _____ is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-97* _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-97 are currently pending.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, 38 and 39, drawn to a fusion protein comprising a soluble trimeric form and a portion of HIV gp41, classified in class 435, subclass 69.7.

II. Claims 41-45, drawn to a D-peptide which comprises WXWL, classified in class 930, subclass 21.

III. Claims 66-71, drawn to a drug (that binds the N-helix coiled-coil cavity of HIV gp41 and inhibits its entry into cells), if peptidic, classified in class 530, subclass 300.

IV. Claims 74-87, drawn to cyclic peptides, classified in class 530, subclass 317.

V. Claims 16-20, drawn to a method of identifying drugs that interfere with C34-N36 complex formation, classified in class 435, subclass 7.1.

VI. Claims 21-24 and 40, drawn to a method of eliciting an immune response through the administration of a peptide comprising a soluble trimeric form and a portion of HIV gp41, classified in class 424, subclass 188.1 and 208.1.

VII.. Claims 25-34, drawn to a method of interfering with HIV entry into a mucosal cell through the administration of a drug that binds to HIV gp41, classified in class 514, subclass 1.

VIII. Claims 35-37 and 46-52, drawn to a method of identifying compounds that bind to HIVgp41 employing D-peptides and other drug candidates, classified in class 435, subclass 7.1.

IX. Claims 53-56 and 60-65, drawn to a method of producing a drug that binds to HIV gp41 , classified in class 514, subclass 1.

X. Claims 57-59, drawn to a method of producing a soluble model of HIV gp41, classified in class 435, subclass 5.

XI. Claims 72 and 73, drawn to a method of identifying a peptide that binds to HIV gp41 using a phage display library, classified in class 435, subclass 7.1.

XII. Claims 88-94, drawn to a method of producing a drug that binds to HIV gp41 using a crystal structure, classified in class 514, subclass 1.

XIII. Claims 95-97, drawn to a method of identifying a molecule that binds to HIV gp41 using a ligand library, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Compound Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to independent and/or patentably distinct compounds which are structurally and/or functionally different (e.g. fusion proteins, cyclic peptides, drugs, D-linear peptides) which are capable of separate manufacture and/or use (e.g. diagnostic assays,

therapeutic treatments, screening assays). Additionally, each of the separate groups require different and separately burdensome manual and/or computer structure and/or bibliographic searches in patent and literature databases.

4. Method Inventions V-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed toward a different methodology that employs structurally and materially different reagents (e.g. fusion proteins, linear peptide, cyclic peptides, drugs), protocols and accomplish different scientific objectives (e.g. drug screening , treatment etc.). Additionally, each of the separate groups require different and separately burdensome manual and/or computer structure and/or bibliographic searches in patent and literature databases.

5. Inventions III and (VII or VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (e.g. drug) as claimed can be used in a materially different process of using that product such as screening assays and therapeutic protocols.

6. Inventions III and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product (e.g. drug) as claimed can be made by another and materially different process such as a synthetic procedure (e.g. solid/liquid phase syntheses) or through extraction of an organic material.

7. Compound Invention III and methods (V/VI/X/XI/XII/XIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case none of the identified methodologies (e.g.V/VI/X/XI/XII/XIII) requires the product (e.g. the drug in Invention III). Each invention is clearly drawn toward a different inventive entity. .

8. Compounds Inventions I/II/IV and methods (V/VI/VII/VIII/IX/X/XI/XII/XIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case none of the identified methodologies (e.g. V/VI/VII/VIII/IX/X/XI/XII/XIII)) requires the product (e.g. of Inventions I, II or III). Each invention is clearly drawn toward a different inventive entity. .

9. Because these inventions are distinct for the reasons given above and:

a. have acquired a separate status in the art as shown by their different classification; and/or

b. the search required for the different groups are different and require independent and separately burdensome manual/computer sequence, bibliographic and classification searches in patent and literature databases and/or

c. have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election: Patentably Distinct

10. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Claim 9, drawn to D-peptides selected from the group consisting of species (a)-(y');

b. Claims 28 and 34, drawn to peptides (a)-(I) and (a)-(y'), respectively;

c. Claims 45, drawn to peptides (a)-(y');

d. Claim 48, drawn to peptides (a)-(y');

e. Claims 74-87, drawn to multiple chemical substitutions.

Each of the identified species is directed toward structurally and/or functionally different peptides or chemical compounds which are capable of separate manufacture and/or use. Separate burdensome manual/computer sequence/bibliographic/classification searches will be required for each species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed peptidic or chemical species (E.g. a single compound) , even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. .

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1627), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)
September 23, 2002

BENNETT CELSA
PRIMARY EXAMINER